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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CRUZ, KATHRIEN ANN	
ART UNIT	PAPER NUMBER
1628	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,020	SALLINEN ET AL.	
	Examiner	Art Unit	
	KATHRIEN CRUZ	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-18 are pending.

Claims 3-6, 8, 11-12 are withdrawn.

Claims 1,2, 7, 9-10 and 13-18 are examined herewith.

Applicants response filed June 18, 2009 has been received and entered in the application.

Priority

The application is a 371 of a PCT/F103/00254 (dated 04/03/2003)

Which claims benefits of provisional application 60/369, 323 (dated 04/03/2002).

Action Summary

Applicant's election with traverse of Group A in the reply filed on January 28, 2009 is acknowledged. The traversal is on the ground(s) that unity was improperly broken. The special technical feature common to claims 1-18 is a method of treating a symptom of disorder or condition associated with sensorimotor gating defects with an alpha-2C-adrenoceptor. This is not a special technical feature because the treatment of symptom of disorder or condition associated with sensorimotor gating defects with an alpha-2C-adrenoceptor alpha-2C-adrenoceptor is known in the prior art. See Haapalinna which treats schizophrenia which is a symptom of schizophreniz is as sensorimotor gating deficits with the administration of alpha-2C-adrenoceptor antagonist.

The requirement is still deemed proper and is therefore made FINAL.

Applicant's response on January 28, 2009 filed in response to the Election/Restriction dated October 31, 2008 has been received and duly noted. The Examiner acknowledges Applicants' election of Group A with traverse. The Applicant argues that the restriction was not appropriate and not burdensome on the Examiner. The Applicant requested that compound/composition, method of treatment and process claims be examined together (Groups A and B) "since the EPO (in the PCT counter part of this application) is a competent search authority and they were able to search the invention..." The Examiner respectfully directs the Applicant to the portions of the MPEP that addresses this issue (see MPEP 1893.03 (e) – below. The invention is restricted according to A) Various symptoms (e.g. agitation, cognitive impairment, etc.) (see claims 2-8). B) Disorders or conditions (e.g. schizophrenia, Tourette's syndrome temporal lobe epilepsy, etc.) (see claims 9-15) due to the fact that they are directed to patentably distinct method of treating distinct disorders.

Respectfully, the Examiner re-asserts that the Election/Restriction was properly restricted.

The examiner may adopt any portion or all of the report on patentability of the IPEA or ISA upon consideration in the national stage so long as it is consistent with U.S. practice. The first Office action on the merits should indicate the report on patentability of the IPEA or ISA has been considered by the examiner. The indication may be a mere acknowledgement.

Thus, the restriction requirement is deemed proper and again **FINAL**.

Claims 1, 2, 7, 9-10 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haapalinna et al (U.S. Patent 5,902, 807) and Pickar et al (U.S. Patent 5,492, 907) and in view of Ludewig (Impaired sensorimotor gating in schizophrenia with deficit and with nondeficit syndrome, Swiss Med Weekly, 2002; 132, 159-165) is withdrawn.

However, due to applicant's amendment of claims, the following rejection is cited below.

Response to Arguments

Applicants argue that no prima facie case of obviousness has been established. This argument has been fully considered but has not been found persuasive. Haapalinna clearly teaches that alpha-2-adrenoceptor antagonist useful for the treatment of a mental illness said antagonist being selective for the alpha-2C-adrenoceptor subtype, in combination with a pharmaceutically acceptable excipient, wherein said composition further comprises a therapeutically effective amount of a different compound wherein said different compound, is an anxiolytic, an antidepressive or an antipsychotic compound. And Pickar clearly teaches a method for treating **schizophrenia and schizoaffective illnesses** comprising the step of administering to a patient in need of such treatment a therapeutically effective amount of an α_2-adrenergic receptor antagonist and a D_2 dopamine receptor antagonist in a pharmaceutically acceptable carrier. And since Parwani teaches that schizophrenia patients are known for having reduced sensorimotor gating (page 667, left column, fifth

paragraph). It would have been obvious to one of ordinary skills in the art to treat sensorimotor gating deficits with an alpha-2C-adrenoceptor. Therefore, the rejection under 35 USC 103 is deemed proper.

Applicants argue that Pickar's teaches away from the instant claims. This argument has been fully considered but has not been found persuasive. Pickar clearly teaches a method for treating **schizophrenia and schizoaffective illnesses** comprising the step of administering to a patient in need of such treatment a therapeutically effective amount of an α_2-adrenergic receptor antagonist and a D_2 dopamine receptor antagonist in a pharmaceutically acceptable carrier. Therefore, the rejection under 35 USC 103 is deemed proper.

Applicants are respectively reminded that arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2, 7, 9-10 and 13-15, 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haapalinna et al (U.S. Patent 5,902, 807) and Pickar et al (U.S. Patent 5,492, 907) both are of record and in view of Parwani (Impaired Prepulse Inhibition of Acoustic Startle in Schizophrenia, Society of Biological Psychiatry, 1999, pages 662-669).

Haapalinna teaches a method for treating mental illness comprises administering a therapeutically effective amount of an alpha-2-adrenoceptor, wherein said alpha-2-adrenoceptor antagonist is selective for the alpha-2C-adrenoceptor subtype. Haapalinna teaches the treatment of cognitive impairment with alpha-2C-adrenoceptor subtype (claim 1 and 11). Haapalinna teaches alpha-2-adrenoceptor antagonist useful for the treatment of a mental illness said antagonist being selective for the alpha-2C-adrenoceptor subtype, in combination with a pharmaceutically acceptable excipient, wherein said composition further comprises a therapeutically effective amount of a

different compound wherein said different compound, is an **anxiolytic, an antidepressive or an antipsychotic compound (claim 8)**. Haapalinna teaches treating a mammal (claim 10).

Haapalinna does not expressly teach that the treatment is for sensorimotor gating deficits.

Pickar teaches a method for treating schizophrenia and schizoaffective illnesses comprising the step of administering to a patient in need of such treatment a therapeutically effective amount of an α_2-adrenergic receptor antagonist and a D_2 dopamine receptor antagonist in a pharmaceutically acceptable carrier (claim 1).

Parwani teahes that sensorimotor gating is assessed by measuring the ability to inhibit the respose to a startling stimulus that is immediately preceded by a weak prestimulus and that these sensorimotor gating are associated with schizophrenia (abstract, page 662, right column, second paragraph). Parwani teaches that schizophrenia patients are known for having reduced sensorimotor gating (page 667, left column, fifth paragraph).

It would have been obvious to one of ordinary skilled in the art at the time of the invention was made to employ the teachings of Pickar and Parwani to that of Haapalinna because Piackar teaches that α_2-adrenergic receptor antagonist is known

to effectively treat schizophrenia and schizoaffective illnesses And Parwani teaches that schizophrenia patients are known for having reduced sensorimotor gating (page 667, left column, fifth paragraph). It would have been obvious to one of ordinary skills in the art to treat sensorimotor gating deficits with an alpha-2C-adrenoceptor.

One of ordinary skill in the art would have been motivated to do so because it is known in the art to use alpha--adrenoceptor to treat individuals suffering with schizophrenia and sensorimotor gating deficits and taking with the fact that alpha-2C antagonists are also known to treat mental illness broadly. It would be obvious to one of ordinary skilled in the art to treat individuals with mental illness such as schizophrenia and sensorimotor gating deficits with alpha-2C-adrenoceptor and another antipsychotic compound as taught by both Haapalinna and Parwani.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haapalinna et al (U.S. Patent 5,902, 807) and Pickar et al (U.S. Patent 5,492, 907) both are of record and in view of Parwani (Impaired Prepulse Inhibition of Acoustic Startle in Schizophrenia, Society of Biological Psychiatry, 1999, pages 662-669) as applied to claims 1, 2, 7, 9-10 and 13-15, 17-18 above, and further in view of Wurster et al (U.S. Patent 6,593,324, with a filing date of 02/28/2001).

Haapalinna, Pickar and Parwani are cited above.

None of cited references expressly teach acridin-9-yl-[4-(4-methylpiperazin-1- yl)-phenylamine.

Wurster et al teaches acridin-9-yl-[4-(4-methylpiperazin-1- yl)-phenylamine (example 12). Wurster teaches a method of treating schizophrenia with an alpha-2 adrenoceptors (claim 15).

It would have been obvious to one of ordinary skills in the art to employ acridin-9-yl-[4-(4-methylpiperazin-1- yl)-phenylamine for the treatment of schizophrenia and sensorimotor gating deficits as taught by Parwani and Wurster. One would have been motivated to employ acridin-9-yl-[4-(4-methylpiperazin-1- yl)-phenylamine for the treatment of schizophrenia and sensorimotor gating deficits because it is known in the art that alpha-2 adrenoceptors are effective in the treatment of schizophrenia and sensorimotor gating deficits often associated with schizophrenia as taught by Wurster Parwani.

For these reasons, the claimed subject matter is deemed to fail to be patentably distinguishable over the state of the art as represented by the cited reference. The claims are therefore, properly rejected under 35 U.S.C. 103.In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Claims 1, 2, 7, 9-10 and 13-15 are rejected.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHRIEN CRUZ whose telephone number is (571)270-5238. The examiner can normally be reached on Mon - Thurs 7:00am - 5:00pm with every Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KATHRIEN CRUZ/
Examiner, Art Unit 1628

/San-ming Hui/
Primary Examiner, Art Unit 1628